



Seborrheic keratosis

Seborrheic keratosis, also known as "Seborrheic keratosis", "barnacle", or "senile wart", develops into an epidermal wart due to benign proliferation of the surface epithelium.

While the cause of this development is yet unknown,1 it is common and increases with age. The prevalence is higher among persons with light skin tones but is evenly distributed among men and women.3

Seborrheic warts vary in appearance and may resemble a flat raisin, from skincoloured to brownish black and between a few millimetres to 3 centimetres in diameter. Larger elements may also occur. They are frequently located on the trunk but also occur on the scalp, face and extremities.1

Seborrheic warts are often asymptomatic but may occasionally require treatment due to uncomfortable itching or for cosmetic reasons.

Seborrheic warts have no malignant potential and can be easily removed.¹



Treatment

Precautions and contraindications

Disposal

What is Hydrozid®

- Hydrozid® is an innovative CE-marked medical device that combines traditional cryosurgery with modern aerosol technology. Its patented, unique application system provides a safe and effective method for treatment of seborrheic warts. Hydrozid® is also approved for the treatment of an additional 10 indications in clinical practice.
- Hydrozid® contains the gas norflurane and exposes the seborrheic wart to temperatures as low as -54°C by means of a concentrated jet.² The varying reaction of skin cells to the low temperatures of cryosurgery enables the treatment of epidermal cells without damaging subcutaneous connective tissue, fibres or immune cells.⁴
- Hydrozid® treatment is based on the methods of *freeze-thaw cycles* and *temperature control*.

 Rather than continuous treatment exposure, studies have shown that repeated exposures to freezing followed





Treatment

Precautions and contraindications

Disposal

by thawing (a freeze-thaw cycle) result in a more consistent and effective treatment.⁵ These cycles also afford the therapist more control of the temperature and its effect on the treated area, which helps prevent overtreatment.⁵

All treatment with Hydrozid® should be adapted to the individual patient.

ADVANTAGES OF TREATMENT WITH HYDROZID® IN CLINICAL PRACTICE

- Ready for use after unpacking no additional preparations required
- Single-hand use for right-handed and left-handed persons alike
- Portable lightweight canister that can easily be transported between treatment rooms
- No personal protective equipment required during treatment⁶
- No obnoxious odours during treatment⁶
- No risk of exposure to harmful substances or materials by inhalation,
 meaning that process ventilation is not required in the treatment room⁶
- No particular requirements for handling and storage: store in an upright position, protected from sunlight and at a temperature below 50°C⁶
- 3 years' shelf life from the production date. Unchanged shelf life after commencement of use⁶

With the 10 other approved treatment indications, Hydrozid® can beneficially be used to treat patients with other therapeutic needs – one medical device to treat patients with 11 different indications.

Treatment

Precautions and contraindications

Disposal

Inform the patient before treatment

Provide the patient with the Hydrozid® patient instructions.

The patient instructions give relevant advice and information in brief about the <u>treatment process</u>.

You can request the patient instructions free of charge from the Hydrozid® customer service: info@hydrozid.eu

TREATMENT

Application template

When treating seborrheic warts, use one of the accompanying application templates to protect the surrounding healthy tissue during treatment.

The application templates have holes in 6 different sizes (3-10 mm in diameter). If the seborrheic wart is larger than 10 mm in diameter, treat the seborrheic wart as described in the treatment section *Treatment of seborrheic warts larger than 10 mm*.

The treatment margins may become blurred during treatment as the formation of ice crystals cover the actual delimitation between the seborrheic wart and the surrounding healthy tissue. The application template can thus help focus on the limits of the seborrheic wart during treatment. You can also use the application templates' size indications to compare the size of the seborrheic wart after each procedure to assess the effect of treatment.

The application templates can be used to treat multiple seborrheic warts on the same patient, after which they must be discarded.



Treatment

Precautions and contraindications

Disposal

TREATMENT STEPS

Treatment of 1 slightly thickened seborrheic wart

After unpacking – do not remove the tip of the application tube. It must remain in place during treament.

1. Release the locking mechanism under the activation arm, from left to right. The canister is now ready to use.

2. Hold the application template in place above the seborrheic wart with your non-dominant hand.

Hold the Hydrozid® canister in your dominant hand as vertically as possible. Push lightly on the canister until you hear a hissing noise and the gas is released. If you push the canister too hard, the sound will be more like when dispensing a deodorant spray, which releases unnecessary amounts of gas with a risk of damaging surrounding healthy tissue. Also, this is not an economical use of the gas.





Treatment

Precautions and contraindications

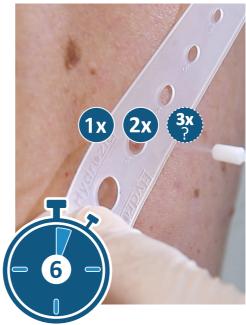
Disposal

3. Spray at a distance of 2-3 centimetres from the seborrheic wart, for up to 6 seconds. A film of white ice crystals will now form in the treated area. Start counting when ice crystals start forming on the seborrheic wart. After (up to) 30 seconds, the ice crystals are no longer white, indicating that the thawing period has ended. The first freeze-thaw cycle is now completed.



4. Then repeat another freeze-thaw cycle. The recommended number of freeze-thaw cycles is 2-3 cycles. The total treatment time is between 12-18 seconds.

The therapist assesses the patient and the treated area between each freeze-thaw cycle and must regard the treatment times as recommendations. Treatment for a longer period than recommended is associated with more frequent and more intense side effects.⁷



Treatment

Precautions and contraindications

Disposal

Treatment of 1 strongly thickened seborrheic wart Combination treatment – cryosurgery and curettage

Cryosurgery is known for its multifarious qualities for treating dermatological lesions.

In addition to the ability of the low temperatures to reduce oedema and bleeding tendencies, cold also has an analgesic effect on skin.8 For the same reason, Hydrozid® is beneficial to use prior to curettage of skin lesions such as seborrheic warts.

If a seborrheic wart is strongly thickened, and to ensure a satisfactory treatment outcome, use curettage to remove the seborrheic wart.

Seborrheic warts that may be candidates for curettage include elements with a diameter of less than 2 centimetres, without the following characteristics:

- located in a risk area (e.g. ear, nose and around eyes and lips)
- recurrence in a previously treated area
- in immunosuppressed individuals
- occurrence in a chronic wound

Treatment steps

Apply cryosurgery treatment using the same procedure as described in treatment steps 1-4 above in the section *Treatment of 1 slightly thickened seborrheic wart*.

Then perform curettage.

Avoid excessively deep curettage due to the cosmetic result. It is an advantage to use a reusable curette as the disposable curette is sharper and entails a risk of deep curettage without being able to sense the delimitation of the seborrheic wart.9

What is **Treatment** Precautions and Disposal Hydrozid® contraindications

Treatment of seborrheic warts in excess of 10 mm

For seborrheic warts with a diameter larger than 10 mm, follow these treatment steps:

After unpacking – do not remove the tip of the application tube. It must remain in place during treatment.

- 1. Release the locking mechanism under the activation arm, from left to right. The canister is now ready to use.
- 2. Hold the Hydrozid® canister in your dominant hand, as vertically as possible. Push lightly on the canister until you hear a hissing noise and the gas is released. If you push the canister too hard, the sound will be more like when dispensing a deodorant spray, which releases unnecessary amounts of gas with a risk of damaging surrounding healthy tissue.
- 3. Spray at a distance of 2-3 centimetres from the centre of the seborrheic wart and continue by constant spraying in circular motions to the edge of the delimitation of the seborrheic wart. A film of white ice crystals will now form in the treated area. The six-second treatment time starts when ice crystals start forming on the seborrheic wart. The entire seborrheic wart must be covered by the ice crystals.
- 4. After (up to) 30 seconds, the ice crystals are no longer white, indicating that the thawing period has ended. The first freeze-thaw cycle is now completed.
- 5. Then repeat another freeze-thaw cycle. The recommended number of freeze-thaw cycles is 2-3 cycles. The total treatment time is between 12-18 seconds.

The therapist assesses the patient and the treated area between each freeze-thaw cycle and must regard the treatment times as recommendations. Treatment for a longer period than recommended is associated with more frequent and more intense side effects.⁷

Treatment

Precautions and contraindications

Disposal

Treatment of 2-4 slightly thickened seborrheic warts

If the patient has 2-4 seborrheic warts, the treatment can be streamlined, as it is possible to treat 2-4 seborrheic warts within the same period of time as it takes to treat one (2×6 seconds - 3×6 seconds). The therapist assesses the patient and the treated area between each freeze-thaw cycle.

As a natural consequence of the low gas temperature, the tip of the Hydrozid® canister will crystallise during prolonged treatment like this and prevent the free flow of the gas for a few seconds and up to minutes at a time.

When treating multiple seborrheic warts, it is therefore advisable to have an additional Hydrozid® canister close to hand to replace the canister first used, until its tip has returned to room temperature and is ready to be used for treatment.

Prepare the canister and place the application template as described in treatment steps 1 and 2 in the above-mentioned section.

Next treatment steps:

- 1. Spray at a distance of 2-3 centimetres from the first seborrheic wart, for up to 6 seconds. Start counting when ice crystals start forming on the seborrheic wart.
- 2. While the ice crystals thaw and the thawing period passes, continue treating the second seborrheic wart.
- Treat the second seborrheic wart using the same procedure. While the ice crystals thaw and the thawing period passes for seborrheic warts 1 and 2, continue treating the third seborrheic wart.
- 4. Treat the third seborrheic wart using the same procedure. While the ice crystals thaw and the thawing period passes for seborrheic warts 1, 2 and 3, continue treating the fourth seborrheic wart.
- 5. Finish by treating the fourth seborrheic wart for 6 seconds using the same procedure.



When the thawing period for the fourth seborrheic wart has passed, the first freezethaw cycle is complete. Now you can start a new freeze-thaw cycle on the first seborrheic wart, followed by the three others.

The recommended treatment time is 2-3 freeze-thaw cycles for each seborrheic wart, corresponding to 12-18 seconds of treatment. The therapist assesses the patient and the treated area between each freeze-thaw cycle.



Treatment

Precautions and contraindications

Disposal

Side effects, healing process and treatment outcome

Cryosurgery therapy may cause a stinging or burning sensation during treatment. Treatment in the area around temples, forehead or scalp may trigger headache in the patient after completed treatment.³

The treated area may appear red, tender and swollen immediately after treatment.

Within 24 hours after the completion of treatment, inflammation develops in response to cell death. This process assists in continuing to break down the seborrheic wart⁹ and is thus a natural reaction during the inflammatory phase of the wound healing process.

Wounds and possibly blisters will subsequently occur in the treated area. ¹⁰ In such cases, the treated area must be protected with a plaster.

After treatment, the patient must keep the treated area clean by washing it daily with water and non-perfumed soap, mornings and evenings.

The patient should avoid exposing the treated area to sunlight for 10-14 days until the treated area is fully healed.

When repeated cryosurgery treatments are needed, it is due to the ability of keratinocytes to insulate the underlying epidermis³ and thus serve as a thermal insulator that can reduce the effect of cryosurgery. The recommended treatment interval for seborrheic warts after the first treatment is 1-2 weeks but should always be adjusted to the individual patient.

The number of treatments depends on the patient's individual clinical response and is assessed by the therapist.

Treatment

Precautions and contraindications

Disposal

Precautions and contraindications

Hydrozid® must only be used by trained healthcare professionals.

Even though the effect of short freezing times as recommended in this material does not result in scarring, ¹⁰ Hydrozid[®] must be used with care to avoid damaging the dermis.

Exercise special caution when applying Hydrozid®:

- near cutaneous nerves, tendons and nail beds¹¹
- in hair-bearing areas. Cryosurgery may result in alopecia areata in exceptional cases⁹
- in persons with impaired arterial or venous circulation¹¹ (e.g. diabetes patients).
- in persons with thin and/or sensitive skin (e.g. elderly with ageing skin, systemic scleroderma, persons treated with inhaled steroids for a prolonged period of time, etc.)
- in persons with dark skin types. Even though the effect of short freezing times as recommended in this material rarely results in pigmentation changes in the treated area, hypopigmentation/hyperpigmentation may occur. This change is seen in persons with dark skin types in particular.¹¹

Do not use Hydrozid®:

- on open skin lesions or eczematous skin to avoid subcutaneous emphysema³
- in patients with cryoglobulinemia, Raynaud's disease, cold urticaria and blood dyscrasias and Pyoderma gangrenosum¹⁰
- in case of uncertain diagnosis of the type of lesion (biopsy for skin carcinoma)¹⁰
- on healthy skin



Disposal

The Hydrozid® canister may be disposed of as normal household waste.

IF YOU HAVE ANY QUESTIONS OR, CONTRARY TO EXPECTATIONS, EXPERIENCE CHALLENGES WHEN USING HYDROZID®

Please contact Hydrozid® customer service by e-mail: info@hydrozid.eu

NOTES

Hydrozid® was developed by the Danish-owned family enterprise BIBAWO Medical A/S, Denmark, and is currently used in 11 countries around the world.

Hydrozid® is approved for the following therapeutic indications:
acrochordon, actinic keratosis, cervical contact bleeding, condyloma acuminatum, gingival melanin hyperpigmentation, seborrheic keratosis, lentigo, molluscum contagiosum, verruca plana, verruca plantaris and verruca vulgaris.

Learn more about Hydrozid® on www.hydrozid.eu

References

- Sundhed.dk Lægehåndbogen [Doctor's Handbook]. Seboroiske vorter. Available: Seboroiske vorter -Lægehåndbogen at sundhed.dk [2019, 28-10-2021].
- Bench-Top Analysis of Thermal Profiles During Use of Hydrozid® and Cool Renewal Aerosol Cryosurgery Devices. Study Report 2020 (Data on file)
- Thai, K-E & Sinclair, R. D., 1999. Cryosurgery of benign skin lesions. Australasian Journal of Dermatology, 1999, 40, pp: 175-186
- 4. Graham GF, Tuchay SM. 2016. Therapeutic Principles and Techniques in a W. Abramovits et al. (eds.), Dermatological Cryosurgery and Cryotherapy. Springer-Verlag London 2016. Chapter 32.
- Sharma VK, Khandpur S. Guidelines for cryotherapy. Indian J Dermatol Venereol Leprol 2009;75(Suppl 2):90-100. Received: August 2008. Accepted: 6 October 2020
- 6. Safety data sheet. Hydrozid® Data Sheet regarding materials safety. 2021
- Lipke, M. 2006. An Armamentarium of Warts Treatments. Clinical Medicine & Research. Volume 4, number 4: 273-293
- Zielinska-Blizniewska, H. & Olszewski, J. 2016. THE USE OF CRYOSURGERY IN OTOLARYNGOLOGY. In: Watson, L. (2016). Cryosurgery and Colposcopy: Practices, Outcomes and Potential Complications. Nova Science Publishers, Inc. Watson, L. 2016. Cryosurgery and Colposcopy: Practices, Outcomes and Potential Complications. New York: Nova Science Publishers, Inc.
- Lamberg A. L & Sølvsten, H., 2010. Curettage af hudtumorer. Ugeskrift for Læger 172/3 18 January 2010, pp: 203-205.
- Andrews, M. D. 2004. Cryosurgery for Common Skin Conditions. AMERICAN FAMILY PHYSICIAN. Volume 69, number 10 / May 15, 2004, pp. 2365-2372
- 11. Sterling J.C et. al 2014, British Association of Dermatologists' guidelines for the management of cutaneous warts 2014. British Journal of Dermatology. 2014, pp. 696–712